8 DISCREPANCIES AND CORRECTIVE ACTIONS

8.1 Overview

8.1.1 Laboratories from time to time will experience technical or administrative case related discrepancies. Such conditions are adverse to the quality of the work product. Discrepancies, as defined by ASCLD/LAB®, can be grouped as minor (Class III) or major (Class I and Class II), depending on the impact of the discrepancy on the Department.

8.1.2 Major discrepancies require management to take positive action in a timely manner. The goals of this corrective action policy are to identify the root cause of a problem, correct the discrepancies and implement a solution to avoid recurrence and maintain an acceptable level of quality.

8.2 Minor Discrepancies

8.2.1 Minor discrepancies generally:

- are foreseeable,
- have a clear-cut immediate cause,
- have a defined straightforward corrective action, which can be adequately documented by a simple entry on the examination documentation, or utilizing the Technical Review Form.
- can be corrected on the spot by the individual who discovers them, and
- have not and will not in any way compromise the quality of work if properly addressed.

8.3 Major Discrepancies

8.3.1 Major discrepancies generally:

- are unexpected,
- require an investigation to determine their root cause,
- require elaborate or intensive action with extensive documentation,
- must be addressed by more than one individual, and
- have compromised the quality of work.

8.4 Corrective Actions – Minor Discrepancies

8.4.1 Corrective actions of minor discrepancies are routinely made by examiners and are considered normal operating procedures.

8.4.2 Individuals will briefly but clearly document the following:

- The discrepancy, and its cause, as necessary
- The corrective action

8.5 Corrective Actions - Major Discrepancies

8.5.1 The individual who identifies a potential major discrepancy shall inform their supervisor in a timely manner. The supervisor shall briefly but clearly document the discrepancy and method of identification in an e-mail to their Laboratory Director and Section Chief, the Director of Technical Services, and the QAC within 2 business days of the identification of the discrepancy.

8.5.2 The Director of Technical Services will determine if the discrepancy is major, and if so, will assign a two-person investigation team to evaluate the discrepancy. The team shall generally include the Section Chief or Laboratory

Director and the supervisor. The QAC will be notified of the team composition and will assign a corrective action tracking designator.

8.5.3 The investigation team will confer with the QAC and applicable Laboratory Director to develop an approach and establish deadlines for the investigation. A tentative corrective action plan or interim status report will be developed by the team and provided to the Director of Technical Services within 30 days of the assignment. Prior to implementation of any corrective action plan, the investigators will determine and document, in a written Corrective Action Report (CAR), the following for review by the QAC and subsequent approval by the Director of Technical Services:

8.5.3.1 The discrepancy itself.

8.5.3.2 The specific event(s) which identified the discrepancy.

8.5.3.3 The extent of the discrepancy.

8.5.3.4 The effect(s) of the discrepancy on the quality of work.

8.5.3.5 Any necessary short term response.

8.5.3.6 The root cause of the discrepancy.

8.5.3.6.1 Root cause identification is commonly perceived as determining assignment of blame. In many cases, an individual may be held responsible for causing a discrepancy, but that is a byproduct of the corrective action process.

8.5.3.6.2 Root cause determination could involve multiple immediate factors.

8.5.3.7 A recommended course of action.

8.5.3.8 A recommended course of follow-up activities.

8.5.4 If the investigation and/or corrective action plan extends over a protracted time period, the investigators will generate regular progress reports to the appropriate Directors and QAC, particularly on completion of milestones.

8.5.5 On completion of the follow-up assessments, the investigators will review the CAR and follow-up documentation, confer with the QAC and applicable Laboratory Director, and make a recommendation in a written summary report to the Director of Technical Services as to the status of the corrective action plan.

8.5.6 The Director of Technical Services either will deem the corrective action completed or specify further action.

8.5.7 The QAC will maintain all original CARs on major discrepancies.

8.5.8 Laboratory Directors will maintain a copy of all corrective action documentation pertaining to their laboratory.

8.6 Special Audit

8.6.1 If the findings of the investigation indicate that there may be a significant problem of non-compliance at a laboratory-wide or a Section level, the QAC will initiate an appropriate audit. The QAC, in consultation with the Director of Technical Services, will assign one or more experienced persons from outside of the suspect Section or laboratory to perform a special audit.

8.6.2 A report from the audit team will be made to the Director of Technical Services who will determine what follow-up action or actions will be carried out.

8.7 Completed Cases Released To Clients

If it is determined that a discrepancy has affected Certificates of Analysis that have been furnished to clients, the concerned Laboratory Director will request resubmission of the appropriate evidence for reanalysis.

► End